



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-1305]

#### Antimicrobial Drug Use in Companion Animals; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is soliciting comments from the public on antimicrobial drug use practices in companion animals and the potential impacts of such uses on antimicrobial resistance in both humans and animals. We are issuing this notice as part of our objective to engage with our stakeholders to develop and implement a strategy for promoting antimicrobial stewardship in companion animals. Specific questions and information requests are included in this notice to help guide input from stakeholders and other members of the public. FDA's Center for Veterinary Medicine (CVM) intends to use the information provided to assist in the development of strategies to promote antimicrobial stewardship in companion animals.

**DATES:** Submit either electronic or written comments on the notice by **[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2021-N-1305 for "Antimicrobial Drug Use in Companion Animals, Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and,

except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Barbara Leotta, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0605, [Barbara.Leotta@fda.hhs.gov](mailto:Barbara.Leotta@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Antimicrobial drugs<sup>1</sup> have been widely used in human and veterinary medicine for more than 80 years, with tremendous benefits to both human and animal health. The development of resistance<sup>2</sup> to this important class of drugs, and the resulting loss of the drugs' effectiveness, poses a serious threat to human and animal health. Because antimicrobial drug use can contribute to the emergence of drug-resistant organisms, these drugs should be used judiciously in both human and veterinary medicine to slow the development of resistance and preserve their utility. While judicious use efforts often focus on antimicrobial drug use in food-producing animal species (e.g., cattle, swine, chickens, and turkeys), there is also a need to better understand how the use of antimicrobial drugs to treat companion animals (e.g., dogs, cats, and horses) might contribute to populations of resistant bacteria in these species and the humans exposed to them.

As part of its regulatory mission, CVM is responsible for ensuring the safety and effectiveness of animal drugs, including antimicrobial drugs, and has taken important steps to update the approved use conditions of medically important antimicrobial drugs (i.e., antimicrobial drugs important for treating human disease) to support their judicious use in animals. CVM believes that the concept of antimicrobial stewardship encompasses several important principles of judicious use that are critical to slowing the rate at which bacteria

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<sup>1</sup> The term "antimicrobial" refers broadly to drugs with activity against a variety of microorganisms including bacteria, viruses, fungi, and parasites. Antimicrobial drugs that have specific activity against bacteria are referred to as antibacterial or antibiotic drugs. The broader term "antimicrobial," however, commonly used in reference to drugs with activity against bacteria, is used in this document interchangeably with the terms antibacterial or antibiotic.

<sup>2</sup> Antimicrobial resistance is the ability of bacteria or other microbes to resist the effects of a drug. Antimicrobial resistance, as it relates to bacterial organisms, occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to treat bacterial infections.

develop resistance to antimicrobial drugs. In simple terms, we believe medically important antimicrobial drugs should only be used in animals when necessary to treat, control, or prevent disease. In addition, when such use is necessary, these antimicrobial drugs should be used in an optimal manner under the oversight of a licensed veterinarian. We acknowledge and support the many efforts that multiple stakeholders and animal health organizations have already taken to promote antimicrobial stewardship practices. For example, the American Veterinary Medical Association defined antimicrobial stewardship as “the actions veterinarians take individually and as a profession to preserve the effectiveness and availability of antimicrobial drugs through conscientious oversight and responsible medical decision making while safeguarding animal, public, and environmental health.”<sup>3</sup>

In September of 2018, CVM published a five-year action plan entitled “Supporting Antimicrobial Stewardship in Veterinary Settings, Goals for Fiscal Years 2019-2023,”<sup>4</sup> which outlines goals and objectives for promoting the judicious use of antimicrobial drugs in animals and includes specific actions CVM intends to undertake in order to carry out those goals and objectives. The purpose of this notice is to address Goal 1 of the five-year action plan, “Align Antimicrobial Drug Product Use with the Principles of Antimicrobial Stewardship,” which includes an objective to engage with our stakeholders to develop and implement a strategy for promoting antimicrobial stewardship in companion animals.<sup>5</sup> One of the actions related to this objective (Action 1.2.1 under Phase 1 Actions<sup>6</sup>) is to obtain public input regarding antimicrobial use practices in companion animals and the impact of such use practices on the development of resistance.

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<sup>3</sup> American Veterinary Medical Association, “Antimicrobial Stewardship Definition and Core Principles,” 2018, <https://www.avma.org/KB/Policies/Pages/Antimicrobial-Stewardship-Definition-and-Core-Principles.aspx>, accessed November 4, 2021.

<sup>4</sup> <https://www.fda.gov/media/115776/download>.

<sup>5</sup> As a part of the plan, CVM established three goals, which include: (1) align antimicrobial drug product use with the principles of antimicrobial stewardship; (2) foster stewardship of antimicrobials in veterinary settings; and (3) enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals. See the five-year action plan at p. 5.

<sup>6</sup> CVM intends to initiate the actions outlined in the plan in two phases, with Phase 1 activities being initiated between FY 2019 and FY 2021 and Phase 2 activities being initiated between FY 2022 and FY 2023. See the five-year action plan at pp. 5-6.

## II. Questions for Consideration

CVM seeks input on the following questions and information requests:

1. Please describe if antimicrobial use practices in companion animals have impacted the development of antimicrobial resistance in bacterial pathogens of companion animals.  
Please provide information, data, and/or references to support your response.
2. Please describe if antimicrobial use practices in companion animals, including extralabel use, have impacted the development of antimicrobial resistance in human bacterial pathogens. If possible, please describe whether the impact was the result of direct or indirect contact between humans and the treated companion animals. Are there specific concerns about the development of antimicrobial resistance in human bacterial pathogens when particular antimicrobial drugs or drug classes are used in companion animals?  
Please provide information, data, and/or references to support your response.
3. How should the human medical importance of particular antimicrobial drugs or drug classes be considered when deciding whether, or under what conditions, to use such drugs in companion animals?
4. How can CVM best engage with our stakeholders on promoting antimicrobial stewardship for companion animals? Examples of stakeholders include other government agencies, the pharmaceutical industry, public health organizations (both public and private entities), veterinary professional organizations, veterinary schools, veterinarians, pet owners, and veterinary diagnostic laboratories.
5. How can CVM encourage the development of antimicrobial drugs consistent with the principles of antimicrobial stewardship for the treatment of infectious diseases in companion animals for which there are no FDA-approved animal drugs?
  - a. What bacterial diseases affecting companion animals are most in need of an FDA-approved animal antimicrobial drug?

- b. What safety and effectiveness study design considerations present challenges for developing antimicrobial drugs to address specific infectious diseases in companion animals (e.g., Lyme disease, sepsis, or osteomyelitis)? Are there alternative study designs that would address these challenges? If not, what role(s) could the stakeholder groups identified in question 4 play in developing such alternative study designs?
  - c. Are there specific infectious diseases in companion animals for which topical formulations of antimicrobial drugs (e.g., medicated shampoos, rinses, or ointments) may be a better alternative than using systemic antimicrobial drugs from the perspective of antimicrobial stewardship? If so, what role(s) could the stakeholder groups identified in question 4 play toward fostering the use of such topical antimicrobial formulations?
6. Labeling:
- a. What information on currently approved animal drug labeling helps the veterinarian prescribe or use an antimicrobial drug in a manner consistent with the principles of antimicrobial stewardship?
  - b. What additional information could be added to the approved animal drug labeling to improve the veterinarian's ability to prescribe or use an antimicrobial drug in a manner consistent with the principles of antimicrobial stewardship?
  - c. Is there a need for materials containing labeling information and/or information about antimicrobial stewardship that veterinarians could provide to the client when they prescribe an antimicrobial drug (e.g., client information sheets or other educational handouts)?
7. With respect to the use of antimicrobial drugs in companion animals, what other actions should CVM consider taking to foster greater antimicrobial stewardship?

Dated: February 9, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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